REMARKS

After entry of the foregoing amendments, claims 36 to 67 will be pending in this application. Claims 66 and 67 are newly added herein. Support for the recitation of leucine as the amino acid may be found in the specification, for example, at page 13, lines 8 to 9 and page 23, Table IV, examples 4 and 5. No new matter is added.

Applicants acknowledge and appreciate the indication in the Office Action dated January 19, 2007 that claims 36 to 65 are allowable over the art of record. Applicants respectfully submit that the added claims, which merely add an additional claim element, are allowable for the same reasons as claims 36 to 65.

Claims 36 to 65 were originally presented in this application by way of a preliminary amendment filed on September 23, 2003. In that amendment, Applicants noted that the claims 36 to 65 were copies or substantially copies of claims 1, 3, 4, 7-9, 11-14, 16-18 and 21 of Reexamination Certificate 6,136,294 C1 ("RE 294"), issued on September 24, 2002. Since the claims were presented within one year of that date, the submission complied with 35 U.S.C. § 135(b)(2) and 37 C.F.R. § 1.607(c).

The Office Action dated January 19, 2007 alleges that Applicants have suggested an interference pursuant to 37 C.F.R. § 41.202(a). Applicants note that none of their previously filed papers in this application contained a request that an interference be declared, or an explicit suggestion of interference pursuant to 37 C.F.R. § 41.202(a). However, regardless of whether Applicants previous submissions and conduct constitute such a request or submission, Applicants hereby explicitly suggest that an interference with RE 294 be declared, and provide the showing required by Section 41.202(a).

1. Patent With Which Applicants Seek an Interference

Applicants suggest that an interference should be declared between the instant application and Reexamination Certificate 6,136,294 C1, issued September 24, 2003 ("RE 294").

2. Identification of Interfering Claims and Proposal of a Count

The interfering claims are claims 36 to 67 of the instant application and claims 1 to 4, 7 to 9, 11 to 18 and 21 to 26 of RE 294.

The claims of both parties are directed to medicinal aerosol formulations, metered dose inhalers, methods of preparation, and methods of treatment. Accordingly, Applicants propose four interference counts, as set forth in Appendix A. The proposed counts are written in the alternative as specifically authorized by the Board in *Hsing v. Myers*, 2 U.S.P.Q.2d 1861, 1862 (Bd. Pat. App. & Int. 1987), where the Board held that it is not improper to have the count in the disjunctive form as long is it is drawn to the same invention claimed by the parties. Although the alternatives set forth in the proposed counts may differ with respect to the specific language employed and with respect to their respective focus on devices or methods, they define substantially the same invention. This is indicated, for example, by the Patent Office's decision to issue composition, device and method claims in RE 294.

The following table identifies the claims that correspond to each proposed count:

Proposed Count	Corresponding Claims of Instant Application	Corresponding Claims of RE 294
Proposed Count 1	36-40, 44, 50-55, 59, 65, 66	1-8, 12, 21-23, 24, 25
Proposed Count 2	46-49, 61-64, 67	14-18, 26
Proposed Count 3	41, 45, 56, 60	9, 13
Proposed Count 4	42, 43, 57, 58	11

3. Claim Chart Comparing A Claim of Each Party to Each Count

Proposed Count 1

Applicants' Claim 65	**RE 294 Claim 1**
A medicinal aerosol formulation which consists essentially of	A medicinal aerosol formulation which consists essentially of
(a) a therapeutically effective amount of a particulate medicament;	(a) a therapeutically effective amount of a particulate medicament;
(b) a propellant; and	(b) a propellant; and
(c) an amino acid	(c) a stabilizer selected from an amino acid, a derivative thereof, or a mixture of the

	foregoing
in addition to the medicament.	whereby said medicament and said stabilizer are different.

Claim 65 of the instant application and claim 1 of RE 294 are interfering because the claim of either party would anticipate the claim of the other party, if it were prior art.

Proposed Count 2

Applicants' Claim 46	**RE 294 Claim 14**
A metered dose inhaler containing a medicinal aerosol formulation	A metered dose inhaler containing a medicinal aerosol formulation
the formulation consisting essentially of	the formulation consisting essentially of
(a) a drug in particulate form in a therapeutically effective amount;	(a) a drug in particulate form in a therapeutically effective amount;
(b) a propellant; and	(b) a propellant; and
(c) a suitable suspension-enhancing amino acid, present in an amount sufficient to prevent settling, creaming or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation,	(c) a suitable stabilizer selected from an amino acid, an amino acid derivative, or a mixture of the foregoing, present in an amount sufficient to stabilize the formulation to prevent settling, creaming or flocculation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation
whereby said medicament and said suspension-enhancing amino acid are different.	whereby said medicament and said stabilizer are different.

Claim 46 of the instant application differs from claim 14 of RE 294 only in that claim 46 recites the presence of a "suspension-enhancing amino acid" rather than a "stabilizer selected from an amino acid." However, both claims recite that the ingredient is present "in an amount sufficient to prevent settling, creaming or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation."

Thus, the "suspension-enhancing amino acid" and "stabilizer selected from an amino acid" elements of the two claims each perform the same function. Moreover, both the instant application (claim 67) and RE 294 (claim 15) recite leucine as a suitable amino acid. Accordingly, Claim 46 of the instant application and claim 14 of RE 294 are interfering, because the claim of either party would anticipate, or at least render obvious, the claim of the other party, if it were prior art.

Proposed Count 3

Applicants' Claim 41	**RE 294 Claim 9**
A method of preparing a medicinal aerosol formulation according to claim 36, which comprises:	A method of preparing a medicinal aerosol formulation according to claim 1, which comprises:
(a) combining	(a) combining
(i) said [particulate]† medicament in an amount sufficient to provide a plurality of therapeutically effective doses	(i) said [particulate]* medicament in an amount sufficient to provide a plurality of therapeutically effective doses
(ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and	(ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and
(c) said suspension-enhancing amino acid, present in an amount effective to enhance the suspension quality of the formulation; and	(iii) said stabilizer [selected from an amino acid, a derivative thereof, or a mixture of the foregoing]* in an amount effective to stabilize the formulation; and
[whereby said particulate medicament and said suspension-enhancing amino acid are different]†	[whereby said particulate medicament and said amino acid stabilizer are different]*
(b) dispersing components (i), (ii) and (iii).	(b) dispersing components (i), (ii) and (iii).

† From dependence on claim 36 * From dependence on claim 1

Claim 41 of the instant application differs from claim 9 of RE 294 in that claim 41 recites the presence of a "suspension-enhancing amino acid" rather than a "stabilizer selected from an amino acid." However, as discussed above, RE 294 equates "stabilizing" with preventing settling, creaming or flocculation of the formulation (*see, e.g.*, 294 patent at col. 1, lines 34 to 39), which corresponds to the "suspension-enhancing" function of the amino acid recited in claim 41 of the instant application. Moreover, both the instant application (*e.g.*,

claim 67) and RE 294 (*e.g.*, claim 15) identify leucine as a suitable amino acid for performing this function. Accordingly, Claim 41 of the instant application and claim 9 of RE 294 are interfering, because the claim of either party would anticipate, or at least render obvious, the claim of the other party, if it were prior art.

Proposed Count 4:

Applicants' Claim 42	**RE 294 Claim 11**
A method of treating in an animal a condition capable of treatment by oral or nasal inhalation	A method of treating in an animal a condition capable of treatment by oral or nasal inhalation
which comprises administering a formulation according to claim 36 to	which comprises administering a formulation according to claim 1
which consists essentially of†	which consists essentially of*
(a) a therapeutically effective amount of a particulate medicament;†	(a) a therapeutically effective amount of a particulate medicament;*
(b) a propellant;† and	(b) a propellant;* and
(c) a suspension-enhancing amino acid†	(c) a stabilizer selected from an amino acid, a derivative thereof, or a mixture of the foregoing*
whereby said medicament and said suspension-enhancing amino acid are different†	whereby said medicament and said stabilizer are different*
to said animal by oral or nasal inhalation.	to said animal by oral or nasal inhalation.

† From dependence on claim 36 * From dependence on claim 1

Claim 42 of the instant application differs from claim 11 of RE 294 in that claim 42 recites the presence of a "suspension-enhancing amino acid" rather than a "stabilizer selected from an amino acid." However, as discussed above, RE 294 equates "stabilizing" with preventing settling, creaming or flocculation of the formulation (*see, e.g.*, 294 patent at col. 1, lines 34 to 39), which corresponds to the "suspension-enhancing" function of the amino acid recited in claim 41 of the instant application. Moreover, both the instant application (*e.g.*, claim 67) and RE 294 (*e.g.*, claim 15) identify leucine as a suitable amino acid for performing this function. Accordingly, Claim 42 of the instant application and claim 11 of RE 294 are

interfering, because the claim of either party would anticipate, or at least render obvious, the claim of the other party, if it were prior art.

4. Detailed Explanation of Why Applicants Will Prevail on Priority

The instant application is a continuation of U.S. Application Serial No. 09/647,331 ("the 331 Application"), filed January 30, 2001, to which no new matter was added. The 331 Application was filed pursuant to 35 U.S.C. § 371 as entry into the U.S. national stage of International Application No. PCT/GB99/01019, filed on April 1, 1999. This international application, in turn, claimed priority to Great Britain Application No. 9807232.5, filed April 3, 1998 ("GB9807232.5"). Priority of GB9807232.5 pursuant to 35 U.S.C. § 119 was properly claimed in both the instant application and its parent 331 application. As the charts which follow will show, the claims of the instant application are supported by both the instant specification and by the disclosure of all priority applications. Accordingly, GB9807232.5, filed April 3, 1998, provides a constructive reduction to practice of the interfering subject matter.

RE 294, on the other hand, is based on U.S. Patent No. 6,136,294, which was filed as U.S. Application Serial No. 09/158,369 on September 22, 1998 with no claim of priority to any earlier application.

Since the instant application is entitled to an accorded benefit that is more than 5 months earlier than the earliest benefit to which RE 294 could be accorded, Applicants will be senior party in the interference, and will prevail on priority unless the presumption due Applicants pursuant to 37 C.F.R. § 41.207(a) is rebutted.

5. Claim Chart Showing Written Description for Each Claim in Specification

The following chart identifies where exemplary support for each of Applicants' claims may be found in the instant specification.

Claim	Exemplary Disclosure in Instant Application[1]
36. A medicinal aerosol formulation, which consists essentially of: (a) a therapeutically effective amount of a particulate medicament;	[0020] According to a first aspect of the present invention there is provided an aerosol composition comprising a propellant and contained therein a first

[1] Citation is to paragraphs numbers from the US publication of the instant application, *i.e.*, US 2005 0249674 A1, published November 10, 2005.

(b) a propellant; and (c) a suspension-enhancing amino acid, whereby said medicament and said suspension-enhancing amino acid are different.	particulate material . . . and a second particulate material . . . [0021] The propellant is in liquid form during storage of the composition and evaporates in use. [0057] Where the first particulate material is a medicament, the second particulate material should be acceptable for administration to a human. [0058] Suitable substances for use as the second particulate material in at least an inhaler may be selected from . . . amino acids. . . [0075]. . . The combination of the first particulate material with the second particulate material both reduces the risk of the first particulate material aggregating undesirably and enhances the dispersement of the particulate medicament in the propellant.
37. The formulation as defined in claim 36 wherein the medicament is selected from the group consisting of albuterol, atropine, beclomethasone dipropionate, budesonide, cromolyn, epinephrine, ephedrine, fentanyl, flunisolide, formoterol, ipratropium bromide, isoproterenol, pirbuterol, salmeterol, amiloride, (-)4-amino-3,5-dichloro-α-[[[6(2-pyridinyl)ethoxy]hexyl]amino]methyl]benzene-methanol, and pharmaceutically acceptable salts, esters, hydrates, and solvates of the foregoing.	[0059] Where the first particulate material is a particulate medicament suitable for oral or nasal inhalation and the aerosol composition is intended for use as an inhaler, examples of suitable particulate medicaments for use in the treatment and prevention of asthma and other conditions associated with reversible airways obstruction include either alone or in any combination: [0060] (i) salbutamol, salbutamol sulphate, mixtures thereof and physiologically acceptable salts and solvates thereof, [0061] (ii) terbutaline, terbutaline sulphate, mixtures thereof and physiologically acceptable salts and solvates thereof, [0062] (iii) beclomethasone dipropionate and physiologically acceptable solvates thereof, [0063] (iv) budesonide and physiologically acceptable solvates thereof, [0064] (v) triamcinolone acetonide and physiologically acceptable solvates thereof, [0065] (vi) ipratropium bromide and physiologically acceptable salts and

	solvates thereof, and [0066] (vii) corticosteriod or bronchodilator. [0067] Other examples of particle medicaments suitable for oral or nasal inhalation by means of the present aerosol composition include: [0068] (viii) peptides, proteins, nucleic acids and derivatives thereof for use in the treatment and prevention of disease states, [0069] (ix) insulin, calcitonin, growth hormone, lutenising hormone release hormone (LHRH), leuprolide, oxytocin and physiologically acceptable salts and solvates thereof for use in the treatment and prevention of disease states including diabetes. [0071] Further examples of appropriate medicaments may additionally be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate,[2] ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline,[3] fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-).sub.4-amino-3,5-dichlor-.alpha.[[[6-[2-(- 2-pyridinyl)ethoxy]hexyl]methyl]benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium,

[2] "Cromoglycate" is another name for cromolyn.
[3] "Adrenaline" is another name for epinephrine.

	tiotropium, atropine or oxitropium; hormones. e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lvsine theophyllinate or theophylline: therapeutic proteins and peptides. e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament. [0072] Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dippropionate and salts or sovates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.
38. The formulation as defined in claim 36, wherein said propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof.	[0075] The propellant is . . . such as 1,1,1,2-tetrafluoroethane (HFA-134a), 1,1,1,2,3,3,3-heptafluoropropane (HFA-227) and mixtures thereof.
39. The formulation as defined in claim 36 wherein said suspension-enhancing amino acid is present in an amount effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formula.	[0025] The presence of the second particulate material in the propellant can lead to flocculation i.e. loose association of the suspended particles into a fluffy floc. Flocculation differs from irreversible aggregation in that it occurs in the secondary energy minimum and is dispersible by hand held shaking. Flocculation of the second particulate material can occur in the propellant either in the absence or in the presence of the first particulate material. Where flocculation occurs in the absence of the first particulate material, the equivalent composition containing additionally the first particulate material can surprisingly inhibit the flocculation occurring. Where flocculation of the second particulate material does however occur in the propellant in the

	presence of the first particulate material it is not detrimental to the present invention as it can be removed by hand held shaking prior to use of the aerosol. It may moreover even be beneficial in preventing irreversible aggregation in the primary energy minimum. [0076] The suitable dispersion characteristics in HFA displayed by the presently provided combination of particulate materials permits its initial dispersion and any redispersion required following sedimenting or creaming with a small energy input, e.g. hand held shaking.
40. The formulation as defined in claim 39 wherein said suspension-enhancing amino acid is present in an amount ranging from about 0.0001% by weight to about 20% by weight based on the weight of the formulation.	[0051] Preferably the weight ratio of the first particulate material to the second particulate material lies in the range 1:0.1 to 1:500 [0052] The total weight of particulate material employed, measured as including dissolved and undissolved material, is thus suitably 20 to 0.001 wt % with respect to the total weight of the composition.[4]
41. A method of preparing a medicinal aerosol formulation according to claim 36, which comprises: (a) combining (i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses; (ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and (iii) said suspension-enhancing amino acid in an amount effective to enhance the suspension quality of the formulation; and	[0029] According to another aspect of the present invention there is provided a method for preparing an aerosol composition comprising: [0030] (a) forming a mixture of a first particulate material . . . and a second particulate material . . .; [0031] (b) dispensing measured portions of respectively said mixture and a propellant into a container; and [0032] (c) sealing the container. [0033] Alternatively all of the ingredients can be admixed prior to dispensing into individual containers.

[4] By way of example, if the total weight of particulate material (including dissolved and undissolved material) is taken as 20% by weight, and the ratio of medicament : suspension-enhancing material is taken to be 1 : 500, the weight percentage of suspension-enhancing material is 19.96% by weight or "about 20%," as recited in the claim. At the other end of the range, if the total weight of particulate material (including dissolved and undissolved material) is taken as 0.001% by weight, and the ratio of medicament : suspension-enhancing material is taken to be 1 : 0.1, the weight percentage of suspension-enhancing material is 0.0001% by weight. *See* Response submitted October 24, 2005, page 11.

(b) dispersing components (i), (ii), and (iii).	[0035] The mixture of the first particulate material and the second particulate material permits ready dosing of the mixture into the container due to improved flow characteristics compared to the first particulate material in the absence of the second particulate material. Suitably the mixture is dosed into the container before the propellant. The enhanced dispersion characteristics of the mixture in the added propellant permits the omission of the step of providing a homogeneous suspension prior to dispensing into a container. In keeping with conventional procedures for preparing an aerosol the container can be sealed following the dosing of the mixture into the container, with the propellant being subsequently dosed into the container through for example an outlet valve forming a part of a seal.
42. A method of treating in an animal a condition capable of treatment by oral or nasal inhalation, which comprises, administering a formulation according to claim 36 to said animal by oral or nasal inhalation.	[0038] According to another aspect of the present invention there is provided a method of administering a particulate material to a patient in need thereof comprising the patient inhaling an aerosol comprising vaporised propellant and a mixture of an active agent comprising particles . . . a second particulate material . . . . In applying the method, forces generated by vaporisation of the propellant separate particulate active agent from the mixture such that the active agent is available and suitable for lung deposition after inhalation. The method can be applied orally or nasally.
43. A method of treating in an animal a condition capable of treatment by oral inhalation, which comprises, administering a formulation according to claim 36 to said animal by oral inhalation.	[0038] The method can be applied orally or nasally.
44. A formulation according to claim 36 in an aerosol canister equipped with a metered dose valve.	[0028] According to another aspect of the present invention there is provided a container containing the aerosol

	composition according to the present invention, the container including a valve outlet. . .Preferably the container includes a metered valve outlet capable of delivering a measured dose of suspension in the form of an aerosol.
45. A method comprising incorporating into a formulation that consists essentially of a propellant and a particulate drug a suspension-enhancing amino acid, in an amount which is effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said drug and said amino acid are different.	[0022] The inclusion of a second particulate material . . . in combination with the first particulate material . . . has unexpectedly been found to enhance dispersion and to reduce particulate aggregation, leading to a reduced risk of irreversible aggregation, whilst still permitting good aerosol performance of the suspension in use. The result is unexpected as prima facie the inclusion of extra insoluble solids had been considered to be inappropriate leading to less desirable aerosol characteristics and poor valve performance due for example to blocking. The present invention can thus permit the delivery of particulate material at a known and consistent concentration. [0025] The presence of the second particulate material in the propellant can lead to flocculation i.e. loose association of the suspended particles into a fluffy floc. Flocculation differs from irreversible aggregation in that it occurs in the secondary energy minimum and is dispersible by hand held shaking. Flocculation of the second particulate material can occur in the propellant either in the absence or in the presence of the first particulate material. Where flocculation occurs in the absence of the first particulate material, the equivalent composition containing additionally the first particulate material can surprisingly inhibit the flocculation occurring. Where flocculation of the second particulate material does however occur in the propellant in the presence of the first particulate material it is not detrimental to the present invention as it can be removed by hand held shaking

	prior to use of the aerosol. It may moreover even be beneficial in preventing irreversible aggregation in the primary energy minimum. [0076] The suitable dispersion characteristics in HFA displayed by the presently provided combination of particulate materials permits its initial dispersion and any redispersion required following sedimenting or creaming with a small energy input, e.g. hand held shaking.
46. A metered dose inhaler containing a medicinal aerosol formulation, the formulation consisting essentially of: (a)a drug in particulate form in a therapeutically effective amount; (b) a propellant; and (c) a suitable suspension-enhancing amino acid, present in an amount sufficient to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said medicament and said suspension-enhancing amino acid are different.	[0124] Example 22 employed ball milled L-Leucine as the second particulate material having a sieve fraction of 90 to 125 μm, and salbutamol sulphate as employed in Example S above. The weight ratio of L-Leucine to salbutamol sulphate was 10:1. The mixture was weighed directly into the canister, the valve crimped, and HFA-134a propellant added in a weight ratio of salbutamol sulphate/leucine: propellant of 1:10. The actuation dose was 100 μg. The unit was briefly hand shaken prior to each firing. [0125] The canister was fired in a pattern designed to imitate the potential use of metered dose inhaler when used by a potential patient. The canister was therefore fired as two shots up to four times daily. Individual shot weights were measured. Aerosol performance and shot potency were determined at the beginning, middle and end of the life of the unit (i.e. on days 0, 20 and 42). [0126] Aerosol performance was assessed by measuring fine particle fraction using a four stage liquid impinger. [0127] Shot potency was determined on individual actuations. [0128] FIG. 3 shows the results of the mean shot weight versus shot number for the canister collected over 42 days, following a nominal actuation timetable of two shots fired four times daily. The shot weights can be seen to be reasonably

	reproducible over the 42 days period and are thus an indicator of valve integrity. Few individual shots lie away the intended shot actuation weight. The variation in a patient actuated device is deemed acceptable. [0129] FIG. 4 shows in diagrammatic form the shot potency i.e. the drug dose per actuation at the start, middle and end of the lifetime testing shown in FIG. 3. The figure shows reproducible and high recovery of the nominal dose at the beginning, middle and end of the unit life, even after storage, when not being tested, at 40.degree. C., 75% R.H. for 42 days. The increased potency of shot 203 is a consequence of a high shot weight. If the potency is normalised for shot weight it is comparable for the data for the other shots in FIG. 4. The data of FIG. 4 indicate that a homogeneous suspension is formed from which representative aliquots are measured. [0130] FIG. 5 shows that good aerosol performance was maintained throughout the life of the canister.
47. The metered dose inhaler as defined in claim 46 wherein said suspension-enhancing amino acid is present in an amount ranging from about 0.0001% by weight to about 20% by weight based on the weight of the medicinal aerosol formulation.	[0124] Example 22 employed ball milled L-Leucine as the second particulate material having a sieve fraction of 90 to 125 μm, and salbutamol sulphate as employed in Example S above. The weight ratio of L-Leucine to salbutamol sulphate was 10:1. The mixture was weighed directly into the canister, the valve crimped, and HFA-134a propellant added in a weight ratio of salbutamol sulphate/leucine: propellant of 1:10. *See also*, citation regarding claim 40, *supra*
48. The metered dose inhaler as defined in claim 46 wherein the medicament is selected from the group consisting of albuterol, atropine, beclomethasone dipropionate, budesonide, cromolyn, epinephrine, ephedrine, fentanyl, flunisolide, formoterol, ipratropium	*See* citation regarding claim 37, *supra*

bromide, isoproterenol, pirbuterol, salmeterol, amiloride, (-)4-amino-3,5-dichloro-α-[[[6(2-pyridinyl)ethoxy]hexyl]amino]methyl]benzene-methanol, and pharmaceutically acceptable salts, esters, hydrates, and solvates of the foregoing.	
49. The metered dose inhaler as defined in claim 46, wherein the propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof.	[0075] The propellant is . . . such as 1,1,1,2-tetrafluoroethane (HFA-134a), 1,1,1,2,3,3,3-heptafluoropropane (HFA-227) and mixtures thereof.
50. A medicinal aerosol formulation which consists essentially of (a) a therapeutically effective amount of a particulate medicament; (b) a propellant; and (c) a suspension-enhancing amino acid, in addition to the medicament.	*See* citation regarding claims 36 or 47, *supra*
51. A medicinal aerosol formulation, which consists essentially of: (a) a therapeutically effective amount of a particulate medicament; (b) a propellant; and (c) an amino acid; whereby said medicament of (a) and said amino acid of (c) are different.	*See* citation regarding claims 36 or 47, *supra*
52. The formulation as defined in claim 51 wherein the medicament is selected from the group consisting of albuterol, atropine, beclomethasone dipropionate, budesonide, cromolyn, epinephrine, ephedrine, fentanyl, flunisolide, formoterol, ipratropium bromide, isoproterenol, pirbuterol, salmeterol, amiloride, (-)4-amino-3,5-dichloro-α-[[[6(2-pyridinyl)ethoxy]hexyl]amino]methyl]benzene-methanol, and pharmaceutically acceptable salts, esters, hydrates, and solvates of the foregoing.	*See* citation regarding claim 37, *supra*

53. The formulation as defined in claim 51, wherein said propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof.	[0075] The propellant is . . . such as 1,1,1,2-tetrafluoroethane (HFA-134a), 1,1,1,2,3,3,3-heptafluoropropane (HFA-227) and mixtures thereof.
54. The formulation as defined in claim 51 wherein said amino acid is present in an amount effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formula.	*See* citation regarding claim 45, *supra*
55. The formulation as defined in claim 54 wherein said amino acid is present in an amount ranging from about 0.0001% by weight to about 20% by weight based on the weight of the formulation.	*See* citation regarding claim 40, *supra*
56. A method of preparing a medicinal aerosol formulation according to claim 51, which comprises: (a) combining (i) said medicament in an amount sufficient to provide a plurality of therapeutically effective doses; (ii) said propellant in an amount sufficient to propel a plurality of said therapeutically effective doses from an aerosol canister; and (iii) said amino acid in an amount effective to enhance the stability of the formulation; and (b) dispersing components (i), (ii), and (iii).	*See* citation regarding claim 46, *supra*
57. A method of treating in an animal a condition capable of treatment by oral or nasal inhalation, which comprises, administering a formulation according to claim 51 to said animal by oral or nasal inhalation.	*See* citation regarding claim 42, *supra*
58. A method of treating in an animal a condition capable of treatment by oral	*See* citation regarding claim 43, *supra*

inhalation, which comprises, administering a formulation according to claim 51 to said animal by oral inhalation.	
59. A formulation according to claim 51 in an aerosol canister equipped with a metered dose valve.	[0028] According to another aspect of the present invention there is provided a container containing the aerosol composition according to the present invention, the container including a valve outlet. . .Preferably the container includes a metered valve outlet capable of delivering a measured dose of suspension in the form of an aerosol.
60. A method comprising incorporating into a formulation that consists essentially of a propellant and a particulate drug, a suitable amino acid in an amount which is effective to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said drug and said amino acid are different.	*See* citation regarding claim 46, *supra*
61. A metered dose inhaler containing a medicinal aerosol formulation, the formulation consisting essentially of: (a) a drug in particulate form in a therapeutically effective amount; (b) a propellant; and (c) an amino-acid present in an amount sufficient to prevent settling, creaming, or flocculation of the formulation for a time sufficient to allow reproducible dosing of the drug after agitation of the formulation, whereby said medicament of (a) and said amino acid of (c) are different.	*See* citation regarding claim 46, *supra*
62. The metered dose inhaler as defined in claim 61 wherein said amino acid is present in an amount ranging from about 0.0001% by weight to about 20% by weight based on the weight of the medicinal aerosol formulation.	*See* citation regarding claim 40, *supra*

63. The metered dose inhaler as defined in claim 61 wherein the medicament is selected from the group consisting of albuterol, atropine, beclomethasone dipropionate, budesonide, cromolyn, epinephrine, ephedrine, fentanyl, flunisolide, formoterol, ipratropium bromide, isoproterenol, pirbuterol, salmeterol, amiloride, (-)4-amino-3,5-dichloro-α-[[[6(2-pyridinyl)ethoxy]hexyl]amino]methyl]benzene-methanol, and pharmaceutically acceptable salts, esters, hydrates, and solvates of the foregoing.	*See* citation regarding claim 37, *supra*
64. The metered dose inhaler as defined in claim 61, wherein the propellant is selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane or a mixture thereof.	[0075] The propellant is . . . such as 1,1,1,2-tetrafluoroethane (HFA-134a), 1,1,1,2,3,3,3-heptafluoropropane (HFA-227) and mixtures thereof.
65. A medicinal aerosol formulation which consists essentially of (a) a therapeutically effective amount of a particulate medicament; (b) a propellant; and (c) an amino acid in addition to the medicament.	*See* citation regarding claims 36 or 47, *supra*
66. The medicinal aerosol formulation according to any one of claims 36, 50, 51 or 65 wherein said amino acid is leucine.	[0058] . . . Preferably the second particulate material is selected from lactose, glucose and leucine and mixtures thereof. *See also*, citation regarding claim 46, *supra*
67. The metered dose inhaler according to claim 46 or 61 wherein said amino acid is leucine.	[0058] . . . Preferably the second particulate material is selected from lactose, glucose and leucine and mixtures thereof. *See also*, citation regarding claim 46, *supra*

6. Chart Showing Where Priority Applications Provide Disclosure of a Constructive Reduction to Practice

As discussed above, the instant application is a continuation of U.S. Application Serial No. 09/647,331 ("the 331 Application"), filed January 30, 2001, to which no new

matter was added. The 331 Application was filed pursuant to 35 U.S.C. § 371 as entry into the U.S. national stage of International Application No. PCT/GB99/01019, filed on April 1, 1999. The disclosure of these three applications is essentially identical. International Application No. PCT/GB99/01019, in turn, claimed priority to GB9807232.5.

The chart that follows identifies where the instant application and GB9807232.5 provide a constructive reduction to practice of subject matter within each of the proposed counts. Since the disclosures of the 331 Application and International Application No. PCT/GB99/01019 are essentially identical to the disclosure of the instant application, to avoid redundancy, cross citation to these two prior applications has been omitted.

Proposed Count	Instant Application	GB9807232.5
Proposed Count 1	Examples 4 and 5 (Table IV), and accompanying text in paragraphs [0101] and [0102]	Examples 4 and 5 and accompanying text at page 17, line 15 to page 19, line 9
Proposes Count 2	Examples 4 and 5 (Table IV), and accompanying text in paragraphs [0101] and [0102]	Examples 4 and 5 and accompanying text at page 17, line 15 to page 19, line 9
Proposed Count 3	Examples 4 and 5 (Table IV), and accompanying text in paragraphs [0101] and [0102]	Examples 4 and 5 and accompanying text at page 17, line 15 to page 19, line 9
Proposed Count 4	Examples 4 and 5 (Table IV), and accompanying text in paragraphs [0101] and [0102], in combination with paragraph [0035] and/or [0038]	Examples 4 and 5 and accompanying text at page 17, line 15 to page 19, line 9, in combination with text at page 7, lines 16 to 25

CONCLUSION

Applicants submit that the foregoing fully complies with the requirements for suggesting an interference in accordance with 37 C.F.R. § 41.202(a). The foregoing further constitutes a *bona fide* effort to respond fully to the Office Action dated January 19, 2007.

If any additional issues remain, the Examiner is invited to contact Applicants undersigned representative at 215.564.8392.

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